DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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WARNING LETTER

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

APR 17 2000

Ref:OC:I1-1854

Mr. S. Francis
Managing Director
Sim-Med Ltd.
Unit 18, Huffwood Trading Estate
Billingshurst
West Sussex, RH14 9UR
United Kingdom

Dear Mr. Francis:

This letter is written to advise you of noncompliances with the Federal laser product performance standard encountered during review of the report on the Gallium Laser Models Lite, Midi, and Elite, dated October 27, 1999, Accession Number 9912482.

1. 21 CFR 1040.10(f)(6). The Sim-Med Gallium Midi and Elite models lack a beam attenuator, required for all Class IIIb and Class IV laser systems.

2. 21 CFR 1010.2. The Sim-Med Gallium Lasers lack a certification label stating that the product complies with the Federal laser product performance standard. The certification represents a testing program that is in accordance with good manufacturing practices.

3. 21 CFR 1010.3. The Sim-Med Gallium Lasers lack an identification label giving the full address of the manufacturing location and date of manufacture.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or from failure to submit required reports. Failure to respond to this letter may be considered to be in violation of section 538(a)(4) of the Act.

This letter is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance programs. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration (FDA). If the causes are determined to be systemic problems you must promptly initiate permanent corrective actions. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within 15 working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged noncompliances do not exist.

2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).

3. Purchaser Notification and Corrective Action - If you neither refute the noncompliances nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.

    a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers

and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.

b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into United States commerce.

In addition, we have the following question and comments:

It is unclear whether the Sim-Med Midi and Elite models incorporate a remote interlock connector, required for all Class IIIb and IV laser systems [21 CFR 1040.10(f)(3)]. Your response in Part 7.5 implies that there is none; however, the Midi and Elite operator's manuals include a diagram of the rear panels and identify a connector socket for a remote interlock.

The remote interlock switch required by 21 CFR 1040.10(f)(3) enables the user to be able to connect the product to a remote barrier interlock, emergency stop switch, or similar device. Please clarify the purpose of these sockets and whether they satisfy the requirement.

We understand that the sales brochures submitted with the report may be intended for the European market; please note that 21 CFR 1040.10(h)(2)(i) requires that a copy of the Warning logotype labels be on specification sheets and promotional brochures.

Your response should be sent to: General Surgery Devices Branch, Division of Enforcement I (HFZ-323), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850 USA. If you have further questions on these requirements, please contact Ms. Cory Tylka of the General Surgery Devices Branch at (301) 594-4595 or FAX: (301) 594-4636.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

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4/18/00